



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,272	09/23/2003	Barnaba Krochmal	1662/546051	6574

26646 7590 08/29/2006

KENYON & KENYON LLP  
ONE BROADWAY  
NEW YORK, NY 10004

EXAMINER
----------

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
----------	--------------

1624

DATE MAILED: 08/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/669,272

Applicant(s)

KROCHMAL ET AL.

Examiner

Brenda L. Coleman

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 30 and 32-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30 and 32-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/2/06</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 30 and 32-52 are pending in the application.

This action is in response to applicants' amendment dated June 20, 2006.

Claims 30, 32-35, 37-46 and 48-52 have been amended.

### *Response to Arguments*

Applicant's arguments filed June 20, 2006 have been fully considered with the following effect:

1. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 1) of the last office action, which is hereby **withdrawn**.
2. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 2a) and 2b) of the last office action, which are hereby **withdrawn**.
3. With regards to the 35 U.S.C. § 102, anticipation rejection labeled paragraph 3) of the last office action, the applicants' arguments have been fully considered, however they were not found persuasive. As stated by the applicants "Kennis discloses an oral solution, capsule, film-coated tablets, injectable solution and suppositories containing any compound of formula I as the active ingredient (Examples 11-15), however, Kennis does not disclose the crystalline form of risperidone contained in the formulations of claims 30, 32-35, 39, 40, 42-46, 50 and 51, and the crystalline forms of risperidone contained the formulations administered in the methods of claims 36-38, 41, 47-49 and

Art Unit: 1624

52". Polymorphs arise when molecules of a compound arrange in the solid state in distinct ways. It is the solid crystalline form of resperidone that possesses the crystalline polymorph characteristics. Thus the pharmaceutical composition must contain a solid form of the crystalline polymorph form of resperidone in the pharmaceutical composition in order that the characteristics of the polymorph to be retained. However, the applicants are not specifically claiming solid pharmaceutical compositions, but a composition comprising a crystalline form of resperidone and a pharmaceutically acceptable carrier and/or a pharmaceutically acceptable excipient. Claims 30, 32-35, 39, 40, 42-46, 50 and 51 fails to specifically claim a solid pharmaceutical formulation.

Claims 30 and 32-52 are rejected under 35 U.S.C. 102(b) as being anticipated by KENNIS et al., U.S. Patent No. 4,804,663, for reasons of record and stated above.

4. The applicants' arguments are sufficient to overcome the objections labeled paragraphs 4) and 5) of the last office action, which are hereby **withdrawn**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1624

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brenda L. Coleman  
Primary Examiner Art Unit 1624  
August 25, 2006